

FEB 24 2006

**510(k) SUMMARY**

ABRACAIR Air Cleaner, QTZ300-60 and QTZ100-24

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR , Part 807.92, Content and Format of one 510(k) Summary.

**1. Submitted By:**

Dr. David Changaris, MD  
Synlabs, Inc.  
204 N. 17<sup>th</sup> Street  
Louisville, Kentucky 40203-1212  
U.S.A.

**2. Contact Person:**

Dr. David Changaris  
801 Barret Avenue  
Louisville, Kentucky 40204  
Tel: 1-502-584-6852 Fax: 1 -502-584-8379  
Cell: 1-502-445-9471

**3. Date Prepared:**

August 16, 2005

**4. Proprietary Name:**

ABRACAIR Air Cleaner, QTZ300-60  
ABRACAIR Air Cleaner, TI 100-30P

**5. Common/Usual Name:**

Air Purifier

**6. Classification Name:**

§ 880.6500 Medical Ultraviolet Air Purifier. A device designed to remove particles from air, as class II devices, product code FRA, and it is reviewed by General Hospital Devices.

**7. Predicate Device:**

AiroCide TiO<sub>2</sub> (K023830)  
Air Purifier 3707 UVC (K033448)

8. **Device Description:**

**ABRACAIR Air Cleaner, QTZ300-60 and QTZ100-24** are devices that use a 6-inch xenon flash lamp, doped with titanium within a reflecting chamber to irradiate air as the air passes through a baffled chamber. An internal fan draws air through a input filter at approximately 300 cubic feet per minute (CFM) or 100 CFM determined by model number.

9. **Intended Use:**

The ABRACAIR Air Cleaner is used to reduce the concentration of viable airborne bacteria, mold and spores within inhabited spaces. The use of this device is not intended to treat a specific disease or medical condition. It should be used as part of a comprehensive air quality program.

10. **Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the ABRACAIR Air Cleaner was tested by the Research Triangle Institute which showed ABRACAIR reduces aerosolized bacteria and fungi. The device has been tested to Underwriter Label safety standards and is eligible to bear the Canadian Standards Association (CSA) Mark with the C-US Indicator.

11. **Substantial Equivalence:**

The **ABRACAIR Air Cleaner, QTZ300-60 and QTZ100-24** are substantial equivalence to AiroCide TiO<sub>2</sub> (K023830) and Air Purifier 3707, UVC (K033448) in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary



FEB 24 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David Changaris  
Chief Executive Officer  
Abracair, Incorporated  
801 Barret Avenue  
Louisville, Kentucky 40204

Re: K052732

Trade/Device Name: Abracair models QTZ300-60 and QTZ100-24  
Regulation Number: 880.6500  
Regulation Name: Medical ultraviolet air purifier  
Regulatory Class: II  
Product Code: FRA  
Dated: December 12, 2005  
Received: February 7, 2006

Dear Mr. Changaris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

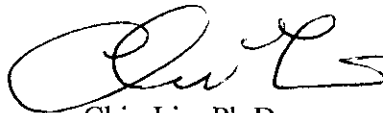
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital ,  
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K052732

Device Name: Abracair models QTZ300-60 and QTZ100-24

Indications For Use: The Abracair Air Cleaner is intended for the reduction of aerosolized mold and bacteria within hospitals, nursing homes, medical facilities. The device may be used in occupied spaces within hospital environments such as baby an/or neonatal nurseries, hospital rooms, operating rooms, mortuaries, embalming rooms.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

\_\_\_\_\_(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Shirley A. M. [Signature]* 2/24/06

Shirley A. M. [Signature]  
General Hospital,  
Dental Services

K052732

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